DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Administration
Rockville MD 20857

April 21, 1999

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

Dear President/CEO:

The purpose of this letter is to request your assistance in assuring the Agency and the American public that your firm has addressed the year 2000 (Y2K) problem as it affects the adequate supply of safe and effective drugs to Americans.

The Y2K problem can cause a variety of errors in how dates are expressed or computed that could adversely affect automated drug process controls and clinical and non-clinical data integrity. Y2K is an issue that, if not addressed, could adversely affect the safety and health of the American public. It is also important that suppliers to your firm have Y2K compliant systems because a disruption in the flow of components, packaging materials, and equipment, for example, could halt or slow pharmaceutical production, even if your firm has Y2K well under control. I therefore urge you to work with your suppliers to ensure there will be a minimum of disruption. Of special concern are manufacturing processes, which if disrupted by Y2K could result in severe shortages of needed pharmaceuticals. An additional concern is the possibility of increased production demands because of distributor and consumer stockpiling of critical supplies and pharmaceuticals.

It is the agency's expectation that manufacturers will do all they can to ensure that their systems are Y2K compliant and give the highest priority to addressing this issue. Manufacturers should thoroughly review and test all computer systems and have appropriate contingency plans in place before January 1, 2000. All procedures to achieve this goal should be appropriately tested and validated prior to implementation. Manufacturers should also establish policies and procedures to monitor consumer demand and to ensure that unwarranted stockpiling beyond normal levels that taxes production capacity does not compromise product availability to all customers.

We request that you complete the attached survey concerning the status of actions taken to address the year 2000 problem. Documentation regarding the steps you have taken to prepare for the year 2000, including this survey, should be available for FDA review during inspections. This special Year 2000 data gathering request is being made pursuant to section 4(f) of the Year 2000 Information and Readiness Disclosure Act. We will use the information you provide to inform the American public about the Year 2000 readiness of the pharmaceutical industry. Therefore, your answers to questions 1, 7, and 8 of the attached survey may be made available to the public via FDA's Internet site (www.fda.gov/cder/y2k). Answers to questions 2 through 6 in the survey will be protected under section 4(f) of the Year 2000 Information and Readiness Disclosure Act. However, aggregate data may be made available to the public.

In order to provide the best service to the industry and public, as well as recognizing the limited time available before the Year 2000, we ask that all manufacturers respond to the attached Y2K

Assessment survey within **15 days of the receipt of this letter to:**

Food and Drug Administration
Center for Drug Evaluation and Research
Attention: Y2K Taskforce; HFD-006
5600 Fishers Lane
Rockville, Maryland 20857

Fax: 301-594-5493

In addition, we ask that you provide us with timely updates on any pertinent Y2K compliance issues that might surface after completion of the attached survey.

On a personal note, I know that you share our commitment to the uninterrupted provision of our nations's vital drug supply. If you have further questions, you may contact Khyati Roberts, Science Policy Analyst, at (301) 594-6779. Thank you for your cooperation.

Sincerely,

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration

Attachment - Y2K Assessment Survey

Y2K Assessment Survey
Center for Drug Evaluation and Research

Name[1] and Address of Company:_____

_____

_____

Name, Title, Phone Number, and Email address of Y2K Coordinator (or contact):

_____
_____

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1. Have you taken all necessary steps to assure that the information technology and automated systems (e.g., manufacturing, quality control, distribution systems) used in the facilities responsible for the safe and effective production and distribution of all of your products that will be distributed in the United States are Y2K compliant?[2] (Please update us when any significant change in your status occurs.)
   _____Yes
   _____No (What date do you anticipate completing this task? _____)

2. Do you plan on having an independent organization (i.e., a group other than the one who did the initial analysis) conduct a review of your Y2K program?
   ____Yes (When will this independent review be completed? _____)
   ____No

3. Do you have foreign suppliers of materials (e.g., raw materials, equipment) used in the manufacture and/or distribution of your products? _____Yes _____No

   a. Have you asked these foreign suppliers of their Y2K readiness?
      _____Yes
      _____No (When will this task be completed? _____)

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[1] If you do business (i.e., distribute your products) under another business name, please also provide that business name(s).

[2] Compliant means that the automated systems can accurately process date/time data (including, but not limited to, calculation, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries, and the years 1999 and 2000 and leap year calculations. This includes identifying all of the systems and correcting and validating any solutions to the problems related to Y2K or implementing workarounds to deal with the problems. In addition, you should have written documentation (e.g., assessments, test results, reports from independent reviewers) to demonstrate that all possible steps have been taken to make the systems compliant or have written documentation of your workarounds.

4. Do you have contingency plans (i.e., a plan to deal with potential problems such as problems in obtaining raw materials or in manufacturing, packaging, labeling, or distributing the finished product)?
_____Yes
_____No (When do you expect to have one in place? _____)

   a. Where appropriate, have the components of the contingency plans been tested?
   _____Yes
   _____No (When do you expect to complete testing? _____)

   b. Do the contingency plans address potential problems with your key business partners (suppliers, vendors, distributors & others)?_____Yes ____No

   c. Do your contingency plans address potential problems with foreign suppliers (e.g., establishment of alternate suppliers of materials)? _____Yes _____No

5. Do you have plans to increase production of your products due to an anticipated increase in consumer demand due to Y2K concerns?
_____Yes _____No

   a. If you face an increase in demand due to Y2K concerns on the part of consumers or actual production or supply problems, is an increase in production feasible at this time (i.e., as of the second quarter of 1999)?
   _____Yes _____No

6. Do you anticipate submitting supplements[3] to address any Y2K manufacturing changes?
_____Yes _____No _____N/A

7. Do you have an Internet site that provides information on the Y2K readiness of your company?
_____Yes (URL:_____)
_____No

8. Do you have a telephone number or other means to handle inquiries from your customers on your Y2K status?
_____Yes (Telephone number:_____)
_____No

_____ _____

President/CEO Date

[3] This question is being asked to help us develop rapid response plans for dealing with a potential increase in the number of supplements that may be submitted for review.